

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

077747-010100

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on May 5, 2010Signature Mari MorrisTyped or printed name Marilyn Morris

Application Number

10/556,481

Filed

11/14/2005

First Named Inventor

Christopher Malyszewicz

Art Unit

1796

Examiner

Hardee, John R.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. 54,919
Registration number _____

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Heath J. Briggs
Signature

Heath J. Briggs

Typed or printed name

303-685-7418

Telephone number

May 5, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Malyszewicz, C. et al.

Serial No.: 10/556,481

Filed: November 14, 2005

Confirmation No.: 1232

Atty. File No.: 077747-010100

For: "ANTI-VIRAL AND ANTI-BACTERIAL CLEANING COMPOSITION"

) Group Art Unit: 1796

) Examiner: HARDEE, John R.

**REMARKS ACCOMPANYING PRE-
APPEAL BRIEF REQUEST FOR
REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

These remarks accompany the Notice of Appeal and corresponding Pre-Appeal Brief Request for Review being filed contemporaneously herewith. In view of the following remarks, reevaluation and reconsideration of the application is requested.

Background

In this case, the Examiner has finally rejected all pending claims (Claim 35, 40-41, 54-55, 64, 66, 73-80) as being obvious using U.S. Patent No. 5,276,047 to Eggensperger et al. ("D1") as the main reference. Because all pending claims exclude the present of BIT, the principal constituent of the D1 composition, the Examiner has improperly rejected the claims.

All pending claims use the transitional phrase "consisting essentially of", thereby excluding the presence of any non-claimed constituents that would affect its basic and novel properties

The present application contains one independent claim (claim 35), which states:

A cleaning solution *consisting essentially of*:

(a) at least one long chain alkyl polyamine of the formula:



wherein R is a linear or branched alkyl amine chain comprising 10 to 14 carbon atoms;

(b) at least one aliphatic alcohol;

(c) iodine;

(d) at least one amphoteric surfactant; and

(e) at least one antioxidant.

Thus, all claims use the transitional phrase “consisting essentially of”.

The Federal Circuit has defined the legal meaning of the phrase “consisting essentially of”:

“‘Consisting essentially of’ is a transition phrase commonly used to signal a partially open claim in a patent. Typically, ‘consisting essentially of’ precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients *that do not materially affect the basic and novel properties of the invention.*”

PPG Industries v. Guardian Industries Corp., 156 F.3d 1351, 1354 (1998). In other words, the phrase “consisting essentially of” renders the claim open *only* for the inclusion of unspecified ingredients which do not materially affect the basic and novel characteristics of the invention. *Ex Parte Hoffman*, 12 USPQ2d 1061, 1063 (BPAI 1989).

D1 requires the presence of BIT -- a material not included in the pending claims

As presented in the Amendment filed October 2, 2009, D1 requires the presence of BIT (1,2-benzisothiazolin-3-one). Furthermore, BIT does not fall into any of the claimed categories (a)-(e) of claim 35. (October 2, 2009 Amendment, pp. 7-8). Therefore, D1 is only relevant if the addition of BIT to the presently claimed solution would affect its “basic and novel” properties.

It is the Examiner’s position that it is Applicant’s burden to show that BIT would affect the basic and novel properties of the claimed composition:

“When applicant contends that additional . . . materials in the prior art are excluded by the recitation of “consisting essentially of”, applicant has the burden of showing that the introduction of additional . . . components would materially change the characteristic of applicant’s invention.” *Final Office Action* of November 6, 2009, pp. 4.

“[T]he claims remain rejected for the reasons of record. Applicant’s arguments regarding “consisting essentially” scope are well taken, but in the absence of evidence regarding how additional materials would affect any alleged “basic and novel properties” of the claimed compositions, whether such evidence is supplied by applicant or otherwise, the examiner is constrained to follow Office policy and maintain the rejections.” *Advisory Action* of January 12, 2010.

However, as shown below, this is an incorrect application of the law.

The law is clear -- once the “basic and novel properties” of a composition are demonstrated, applicant need not test variants of the prior art

As presented in the Amendment of January 5, 2010, the law is clear on the burden of proof relating to the phrase “consisting essentially of.” Once the basic and novel properties of a

composition have been demonstrated, Applicant *is not* required to test variants of the prior art. This is best illustrated by *In re de Lajarte*, 143 USPQ 256 (BPAI 1964), which was cited by the Examiner, and is still good law today.

In *In re de Lajarte*, the applicant claimed a glass composition that excluded the presence of sulfur and carbon via the use of the “consisting essentially of” transition. The applicant had provided evidence that his claimed composition had better increase in resistance to perforation, but did not have evidence regarding whether sulfur or carbon would change the basic and novel characteristics of his claimed glass. In overturning the rejection by the Board and the Examiner, the CCPA stated:

“The solicitor would put the burden of showing a material change on the appellant. . . . [H]ere appellant has the burden of showing the basic or novel characteristics of his insulating glass. ***He has met his burden by pointing out in his specification and claims the great increase in resistance to perforation resulting from his composition.***”

The Board of Appeals and the solicitor contend that appellant has furnished no evidence that a critical difference in appellant’s emphasized characteristics would result from the introduction of small amounts of Lyle’s coloring agents, charcoal and sulfur. ***It is not clear what evidence they would require.*** The solicitor has noted that an affidavit which the board did not consider contains nothing significant on this issue. It may be implied that the Patent Office would require appellant to duplicate the Lyle glass and compare its resistance to perforation with that of appellant’s glass.

In the total absence of evidence in the record to indicate that the amber glass disclosed by Lyle would be expected to have desirable electrical insulating properties, ***we can find no justification for placing the burden on applicant to conduct experiments to determine the insulating properties of the colored glass disclosed by Lyle. Although there are only very slight differences between the Lyle composition and that sought to be patented, we cannot assume that these small differences are incapable of causing a difference in properties. Appellant, in showing that his glass has basic and novel properties (at least as far as the record is concerned), would appear to have met his burden.***” (emphasis added).

Id. at 258-259. In other words, once an Applicant has shown the basic and novel properties of his composition, the Patent Office **cannot** place “the burden on an applicant to conduct experiments” to demonstrate patentability relative to other prior art compositions.

The basic and novel properties of the presently claimed composition have been demonstrated, and therefore, the present claims are patentable over D1

As presented in the amendment of January 5, 2010, the specification of the patent application illustrates the basic and novel properties of the presently claimed composition. For example, the

presently claimed composition is especially useful in neutralizing viruses. As described in PARA. 0046-0049 of the application, when the claimed solution is "suitably buffered", the claimed long-chained alkyl triamine (claim element (a)) forms a cationic species. Together with the claimed amphoteric surfactant (claim element (d)), the triamine appears to attack the outer wall of the capsid of the virus. (PARA. 0048) In other instances, the buffered cationic triamine may bond to the outer surfaces of the virus, preventing replication. (PARA. 0049) The claimed triamine and/or amphoteric surfactant also may bind to critical parts of the DNA/RNA, resulting in an inability of the virus to replicate. (PARA. 0048) The claimed iodine (claim element (d)) and/or aliphatic alcohol (claim element (b)) of the claimed solution may complex with the DNA and/or RNA of the viruses. (PARA. 0048) The antioxidant helps stabilize the solution (claim element (e)). (PARA. 0043) The results provided for in PARA. 0053-0058, and illustrated in FIG. 1, show the efficacy of the claimed composition in neutralizing viruses.

Furthermore, the virus neutralizing capabilities of the composition are also claimed. Dependent claim 64 specifically provides that the composition "is configured to rupture the phospholipid membrane of the bacteria or virus". Dependent claim 66 specifically provides that the composition "is configured to substantially permanently encapsulate the bacteria or virus and prevent replication of their genetic material." These dependent claims make the current situation even more similar to that of *de Lajarte*, who claimed the electrical characteristics of his glass (U.S. Patent No. 3,252,812). Issued claim 3 of *de Lajarte* is representative and corresponds to pending claim 11 discussed in the CCPA decision. *de Lajarte* claim 3 states: "Electrically resistant glass . . . having a resistance to perforation equivalent to at least 20 kv in a plate 500 x 500 x 7 mm at 200°C, under sine wave current of 50 periods, and having a composition consisting essentially of . . . [claimed composition and ranges]" The CCPA held that this was sufficient to establish the basic and novel properties of the claimed composition ("He has met his burden by pointing out in his specification and claims the great increase in resistance to perforation resulting from his composition." *Id.* at 258).

Additionally, as in *de Lajarte*, there is no evidence that the prior art composition would achieve the same virus neutralizing capabilities as the presently claimed composition. This seemed important to the CCPA:

In the total absence of evidence in the record to indicate that the amber glass disclosed by Lyle would be expected to have desirable electrical insulating properties, we can find no justification for placing the burden on applicant to conduct experiments . . ." *Id.* at 259.

D1 provides no evidence that its composition, which requires the presence of BIT, would be useful in neutralizing viruses. D1 discusses the use of BIT as a microbial agent, i.e., bacteria neutralizing (Col. 1, Background). As readily recognized by those skilled in the art, bacteria and viruses are completely separate categories of living organisms. Bacteria are a large group of unicellular, prokaryote, microorganisms, typically a few micrometres in length and having a wide range of shapes, ranging from spheres to rods and spirals. On the other hand, a virus is a small infectious agent, and the shapes of viruses range from simple helical and icosahedral forms to more complex structures. Most viruses are about one hundred times smaller than an average bacterium. For many reasons, compositions that are effective at neutralizing bacteria are not necessarily effective at neutralizing viruses. For example, antibacterial drugs (e.g., penicillin) are generally not useful as antiviral drugs (e.g., AIDS and HIV drugs).

In sum, Applicants have shown that the presently claimed composition realizes basic and novel properties relative to neutralizing viruses. Furthermore, there is no evidence that the composition of D1 would be effective at neutralizing viruses. Hence, based on the prevailing case law, Applicants are not required to conduct further experiments to determine whether additional materials, such as BIT, would affect the basic and novel properties of the presently claimed solution.

Conclusion and reservation of rights

In light of the above remarks, it is respectfully submitted that the presently pending claims are patentable over D1. Furthermore, for efficiency purposes, Applicant has not addressed (i) the non-combinability of D1 with U.S. Patent No. 6,387,586 (*see*, RCE of 5/6/09, and Response of 10/6/08), or (ii) the Examiner's failure to establish a *prima facie* case relative to claims 64 or 66 (*see*, Office Actions of 6/5/09, pp. 5, and 8/27/07, pp. 6, and RCE of 5/6/09, pp. 8-9). However, Applicant reserves the right to do so should this case advance to Appeal.

Respectfully submitted,

Date:

May 5, 2010

GREENBERG TRAURIG, LLP

Heath J. Briggs

Heath J. Briggs

Attorney for Applicant

Registration No. 54,919

1200 17th Street, Suite 2400

Denver, CO 80202

Phone: (303) 572-6500; Fax: (303) 572-6540